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of

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for

COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH

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1 peroxide salts of the alkali or alkaline earth metals and peroxyacetic acid ($\text{CH}_3\text{C}=\text{OO}-\text{OH}$)
2 are known to be useful in whitening teeth.

3 The most commonly used dental bleaching agent is carbamide peroxide
4 ($\text{CO}(\text{NH}_2)_2 \cdot \text{H}_2\text{O}_2$), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and
5 perhydrol-urea. Carbamide peroxide has been used by dental clinicians for several decades
6 as an oral antiseptic. Tooth bleaching was an observed side effect of extended contact time.
7 Over-the-counter compositions of 10% carbamide peroxide are available as GLY-OXIDE®
8 by Marion Laboratories and PROXIGEL® by Reed and Carnrick. A sticky bleaching gel
9 which is able to hold a comfortable-fitting dental tray in position for an extended time period
10 is available under the trademark OPALESCENCE® from Ultradent Products, Inc. in South
11 Jordan, Utah.

12 Patients who have desired to have their teeth whitened have typically done so by
13 applying a bleaching composition to the teeth by means of a dental tray for repeated
14 treatments, or they have had to submit to conventional in-office bleaching techniques that
15 required from 4 to 10 visits to the dental office before clinically significant results were
16 achieved. Clinically significant results are quantifiable such as by measuring gray scale, L*,
17 and as to yellowness or blueness, b*, in the CIE® system of color measurement or by
18 equivalent methods.

19 Although dental bleaching compositions are effective in removing stains and
20 superficial discoloration, they are often limited by the inherent translucence of many people's
21 teeth. More precisely, teeth having more translucent enamel are difficult to whiten beyond
22 a certain point since the yellowish or grayish tint of the underlying dentin is difficult to
23 change by bleaching alone.

24 Another downside of tooth bleaching regimens is the tendency of tooth bleaching
25 agents to cause increased sensitivity when applied to teeth over prolonged periods of time.
26 Thus, attempts to further whiten a person's teeth, including prolonged bleaching of

1 excessively translucent teeth, may result in increased tooth sensitivity, which can become
2 quite severe for some people.

3 From the foregoing, it will be appreciated that what is needed in the art are improved
4 compositions and methods for whitening teeth, including improved compositions and
5 methods for opacifying translucent teeth.

6 It will also be appreciated that what is also needed are improved compositions and
7 methods for whitening and opacifying teeth which reduce tooth sensitivity, compared to
8 conventional dental bleaching compositions.

9 Such compositions and methods for bleaching, whitening and opacifying teeth, while
10 reducing tooth sensitivity, are disclosed and claimed herein.
11

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

The present invention generally relates to dental whitening compositions and methods for whitening teeth. In addition, the present invention relates to compositions and methods that result in reduced tooth sensitivity compared to conventional dental bleaching compositions. The compositions of the present invention include a dental bleaching agent in combination with potassium nitrate (KNO_3), which acts both as a desensitizing agent and as an opacifying agent that reduces the translucency of tooth enamel. Whereas it was known that potassium nitrate is effective as an anesthetic in order to reduce tooth sensitivity, it was not heretofore known that potassium nitrate also enhances tooth whitening when used in a dental composition in combination with a bleaching agent.

The potassium nitrate and bleaching agent are typically dispersed in a liquid or gel carrier. In addition, the whitening compositions may include one or more other dental agents, such as an anticariogenic agent for reinforcing teeth against tooth decay or an antimicrobial agent for treating gum diseases. The most commonly used anticariogenic agents include fluoride salts, such as stannous or sodium fluoride, which can also impart antide-mineralization or even remineralization properties to the tooth whitening compositions. Examples of preferred antimicrobial agents include chlorohexidine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methyl benzoate, and propyl benzoate.

The compositions are preferably substantially free of abrasives, as the compositions are typically not scrubbed onto the teeth. When using abrasive toothpastes, people typically brush for less than 60 seconds, which is not enough time to cause a noticeable whitening effect. On the other hand, scrubbing teeth with an abrasive material for an extended period of time can be harmful to the tooth enamel. Therefore, in order to allow for extended bleaching, whitening and opacification of teeth, the inventive compositions will preferably not include substantial quantities of an abrasive.

1 POLYOX®, a mixture of polyethylene oxides having a molecular weight of 100,000-
2 8,000,000 and available from Union Carbide, including higher molecular weight
3 polyethylene glycols, or any compositional or chemical equivalents of the foregoing.
4 PEMULEN® is a propriety formula that includes a significant quantity of a polyacrylic
5 copolymer that has a slightly hydrophobic end and a strongly hydrophilic end.

6 In addition to glycerin, many other polyols may serve as suitable solvents. The
7 solvent may also be water alone or in combination with a polyol. Glycerin is a preferred
8 solvent as it works well in forming a sticky gel with carboxypolymethylene. Glycerin also
9 provides some flavor enhancement. A few possible substitutes for glycerin include
10 propylene glycols, polypropylene glycol, polyethylene glycols, erythritol, sorbitol, mannitol,
11 other polyols, and the like. In some embodiments polyols such as glycerin, lower molecular
12 weight polyethylene glycols, polypropylene glycol, propylene glycol, and sorbitol may also
13 be used without a tackifying agent.

14 As indicated hereinabove, one currently preferred sticky matrix material includes a
15 mixture of carboxypolymethylene together with other suitable admixtures. The term
16 "carboxypolymethylene" is used to denote a broad category of polymers, particularly
17 copolymers of acrylic acid and polyallyl sucrose. Because carboxypolymethylene that has
18 not been completely neutralized includes active carboxylic acid groups or moieties,
19 carboxypolymethylene can be classified as a weak acid. When dispersed in water,
20 carboxypolymethylene can have a pH as low as about 2.5.

21 Because highly acidic compositions can etch teeth, it is generally preferable to adjust
22 the pH of dental compositions that include carboxypolymethylene or other acids to make
23 them less acidic. Accordingly, it is preferable to adjust the pH of the bleaching compositions
24 to within a range from about 4 to about 9, more preferably to within a range from about 5 to
25 about 8. Because it is contemplated that the carboxypolymethylene used in the matrix
26 material and the compositions of the present invention will be mixed with a base to raise the

1 pH of the resulting dental composition, for purposes of the specification and the appended
2 claims, the term "carboxypolymethylene" shall include carboxypolymethylene within
3 compositions at any pH. Preferred bases used to adjust the pH of the dental compositions
4 may include inorganic bases such as sodium hydroxide or ammonium hydroxide.
5 Alternatively, the base may include an organic base such as triethanolamine or other organic
6 amines.

7 Since peroxides may cause irritation and also greater sensitivity in teeth for some
8 people, the simultaneous inclusion of potassium nitrate can offset the potentially negative
9 effects of the peroxide. Accordingly, potassium nitrate can simultaneously provide both
10 opacification and desensitization. Even though other desensitizing agents can also be used
11 to desensitize teeth, including citric acid, citric acid salts, strontium chloride, and the like,
12 only potassium nitrate has been proven to also enhance tooth whitening. Since the present
13 invention allows for prolonged contact via the use of an appropriate tray and/or a sticky
14 composition, the potassium nitrate is preferably included in an amount of about 0.01% to
15 about 2% by weight of the dental composition, and more preferably in an amount of about
16 0.05% to about 1% by weight. Surprisingly, dental bleaching compositions that include only
17 0.5% potassium nitrate have been found to be far superior to compositions that include 3%
18 potassium nitrate, both in enhancing whitening and also in desensitizing teeth.

19 In a preferred embodiment, the opacifying dental compositions within the scope of
20 the present invention will be sufficiently sticky and generally viscous such that positive
21 pressure is needed to dispense them from the container; gravity is not sufficient. Unlike
22 conventional low-viscosity compositions such as GLY-OXIDE (manufactured by Marion
23 Laboratories) or PROXIGEL (manufactured by Reed and Carnick according to U.S. Patent
24 No. 3,657,413 to Rosenthal), preferred whitening compositions according to the present
25 invention will be packaged within a syringe, squeezable tube, or other similar positive
26 pressure dispensing device.

1 An improved dental tray that is thin-walled, flexible and lightweight for holding the
2 dental composition adjacent to a person's teeth is preferably used in combination with sticky
3 and viscous dental whitening compositions of the present invention. The general process for
4 preparing such dental trays is as follows. First, an alginate impression which registers all
5 teeth surfaces plus the gingival margin is made and a stone cast is made of the impression.
6 Optional reservoirs can be prepared by building a layer of rigid material on the stone cast on
7 specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified
8 cast using a thin, flexible plastic sheet material. Once formed, the tray is preferably trimmed
9 barely shy of the gingival margin on both the buccal and lingual surfaces of the person's
10 teeth. The resulting tray provides a comfortable fit of the person's teeth, with optional
11 reservoirs or spaces located where the rigid material was placed on the stone cast. The trays
12 can optionally overlap the gums if desired to provide contact between the dental
13 compositions and a person's gums. The trays of the present invention have greatly increased
14 comfort and exert little or no significant mechanical pressure on a person's teeth or gums.
15 Instead, sticky dental compositions within the scope of the invention can act like a glue to
16 hold the improved trays in place.

17 The amount of tooth whitening obtained through the use of the inventive
18 compositions and methods is dependent primarily upon (1) the length of time each day the
19 tray is worn; and (2) the number of days the tray is worn. The treatment schedule may be
20 tailored to each person's lifestyle or response to the treatment and can be performed as often
21 as a person desires to provide effective relief from excessively translucent teeth. It has been
22 found that treatment during sleep is a good treatment period since there is less mouth activity
23 which causes less whitening composition to be pumped from the tray.

24 In short, the desensitizing bleaching compositions according to the invention include
25 a dental bleaching agent (*e.g.*, carbamide peroxide) in an amount so as to effect bleaching of
26 a person's teeth, typically by maintaining the dental composition in contact with the person's

teeth for at least about 15 minutes, more preferably for at least about 1 hour. They also include potassium nitrate in an amount so as to both reduce sensitivity that may be caused by contacting the dental bleaching agent with a person's teeth and also to enhance the whitening effect of the dental bleaching agent. By means of a comparative study discussed below, the inventors discovered the surprising and unexpected result that the desensitization and enhanced whitening properties of potassium nitrate are actually higher when included in lower concentrations (*e.g.*, 0.5%) rather than at higher concentrations (*e.g.*, 3%).

Moreover, the compositions of the present invention should be contrasted with conventional desensitizing tooth paste compositions formulated with large quantities of abrasives (*e.g.*, 20% or more by weight) and high concentrations of potassium nitrate (*e.g.*, up to 10% by weight) which are intended to contact the teeth during daily brushing (typically for 60 seconds or less). Such compositions are formulated to treat past, rather than prospective, tooth sensitivity. They do not treat sensitivity caused by simultaneous contact of the teeth with a dental bleaching agent, particularly since no significant bleaching and sensitization of a person's teeth are likely using peroxide-containing toothpastes due to the extremely short contact times.

Accordingly, an object of the present invention is to provide improved compositions and methods for whitening teeth, including compositions and methods for opacifying excessively translucent teeth.

It is another object to provide compositions for whitening and opacifying teeth which reduce tooth sensitivity compared to conventional dental bleaching compositions.

These and other objects and features of the present invention will become more fully apparent from the description as follows, or may be learned by the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a stone cast of a person's teeth with a coating being applied to selected teeth surfaces.

Figure 2 is a perspective view of the stone cast of Figure 1 with a dental tray formed from the cast and trimmed below the gingival margin.

Figure 3 is a cross-sectional view taken along line 3-3 of Figure 2.

Figure 3A is an enlarged close-up view taken within the section line 3A-3A of Figure 3.

Figure 4 is a cross-sectional view taken along line 4-4 of Figure 2.

Figure 5 is a perspective view of the opacifying composition being delivered from a syringe into a thin-walled, flexible dental tray.

Figure 6 is a perspective view of a thin-walled, flexible dental tray filled with the opacifying composition just before being positioned on a person's upper arch.

Figure 7 is a perspective view of a thin-walled, flexible dental tray filled with the opacifying composition positioned on a person's upper arch.

1 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

2 As summarized above, the present invention generally relates to dental bleaching
3 compositions and methods for whitening and opacifying teeth, while also minimizing or
4 eliminating tooth sensitivity. At a minimum, the inventive compositions will include a
5 dental bleaching agent and potassium nitrate, which acts as both a whitening/opacifying
6 agent and as a desensitizing agent. The bleaching agent and potassium nitrate are delivered
7 to the teeth by means of a carrier, preferably a carrier that is a sticky matrix. Although
8 potassium nitrate is known as an effective desensitizing agent when used in toothpastes at
9 higher concentrations (*e.g.*, 5% or more), it has surprisingly been found that its effectiveness
10 as a desensitizing agent when used in combination with a dental bleaching agent actually
11 *increases* when used in very low concentrations (*e.g.*, about 0.01% to about 2%). It also
12 more effectively increases the tooth whitening effect of the bleaching agent at such lower
13 concentrations, which is also a surprising result. The compositions preferably do not include
14 an abrasive.

15 In a preferred embodiment, the dental whitening compositions will be used in
16 conjunction with a thin, flexible, comfortable-fitting dental tray in order to hold the
17 compositions against the person's teeth. Preferred dental trays will conform to the size and
18 shape of a person's teeth and will exert little or no significant mechanical pressure onto the
19 person's teeth and/or gums. This makes them more comfortable and pleasant to use
20 compared to conventional dental trays. Nevertheless, the inventive tooth whitening
21 compositions may certainly be used with conventional dental trays, or with no tray at all.

22 In the case where a thin, flexible dental tray is used, the potassium nitrate, dental
23 bleaching agent and optional dental agents will preferably be dispersed in a sticky matrix
24 material capable of exerting a glue-like action such that the whitening composition can
25 adhere and retain the tray in place over a person's teeth without significant mechanical
26 pressure by the tray. The tooth whitening/desensitizing compositions may alternatively be

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It is believed that other carboxypolymethylene resins, such as CARBOPOL 940, may be substituted for CARBOPOL 934P or CARBOPOL 974P NF. CARBOPOL 934P and CARBOPOL 974P NF are currently preferred because they are obtainable in a pharmaceutical grade.

1 The amount of carboxypolymethylene within the inventive dental whitening
2 compositions can vary depending on the desired level of stickiness and also the identities and
3 amounts of the other components within the dental composition. In general, the dental
4 whitening/desensitizing compositions of the present invention will preferably include
5 carboxypolymethylene in a concentration in a range from about 0.5% to about 25% by weight
6 of the dental whitening composition, more preferably in a range from about 2% to about 12%
7 and most preferably in a range from about 3% to about 10%. Where is it desired to increase
8 the stickiness, viscosity and resistance to dilution to saliva, one may adjust the concentration
9 of carboxypolymethylene to achieve a desired level of any or all of these properties.
10 Increased stickiness assists in retaining the preferred dental trays against a person's teeth.
11 Alternatively, compositions can be made less adhesive and tacky if desired, particularly is
12 applied directly without a dental tray.

13 It should be understood, however, that the actual amount of carboxypolymethylene
14 is not critical for obtaining a sticky, viscous dental composition. For example, the sticky
15 matrix material may include other tackifying components that in combination with, or in lieu
16 of some or all of, the carboxypolymethylene will yield a dental whitening composition
17 having the desired level of stickiness needed to hold a preferred, comfortable-fitting dental
18 tray in place over a person's teeth. Other synthetic polymers and/or natural gums, proteins,
19 or other gel-forming admixtures can be used so long as they yield a sticky dental whitening
20 composition.

21 In order to obtain good dispersion of the carboxypolymethylene resin within the
22 dental whitening composition, it is recommended that the carboxypolymethylene be mixed
23 with a suitable solvent before attempting to add other components that are less compatible
24 with carboxypolymethylene, such as water. Examples of suitable solvents for use with
25 carboxypolymethylene include glycerin, polyalkylene glycols, other polyols, and the like.
26 Glycerin appears to enable larger quantities of carboxypolymethylene to be dispersed in

1 cases. Although measuring the pH in anhydrous compositions is generally meaningless, the
2 theoretical pH becomes relevant when an anhydrous dental composition is applied to a
3 person's teeth, which are bathed in water-containing saliva. It appears, based upon clinical
4 and *in vitro* testing, that dental whitening compositions with a pH below about 5 are able to
5 etch enamel. To avoid etching enamel, it is preferable to add a neutralizing agent, or more
6 specifically, a base in order to raise the pH of the inventive dental whitening compositions
7 to within a pH range of about 4 to about 9, preferably to within a range of about 5 to about
8 8, and most preferably a pH from about 6 to about 7.

9 Inorganic and organic bases may be used to raise the pH, with the use of
10 concentrated aqueous sodium hydroxide (50% NaOH in water) being one currently preferred
11 embodiment. In addition to sodium hydroxides, other inorganic bases may be used such as
12 potassium hydroxide and ammonium hydroxide. Examples of suitable organic bases include
13 alkyl amines such as triethanolamine, di-isopropanol amine and other similar amines. The
14 amount of neutralizing agent or base to be included will generally depend on the desired pH
15 and the amount of carboxypolymethylene in the dental whitening composition. Accordingly,
16 neutralizing agents or bases are preferably included in a range from about 1% to about 12%
17 by weight of the dental whitening composition, more preferably in a range from about 2%
18 to about 8% by weight and most preferably in a range from about 3% to about 7% by weight.

19 The term "carboxypolymethylene" shall be understood to include carboxypoly-
20 methylene resins regardless of the pH of the overall dental composition. In other words, the
21 term "carboxypolymethylene" broadly includes resins that have been mixed with a base to
22 raise the pH of the compositions. Moreover, the term "carboxypolymethylene" shall broadly
23 include carboxypolymethylene resins that have reacted with, formed complexes with, or
24 otherwise been altered in any way by other components within the dental whitening
25 compositions of the present invention so long as the carboxypolymethylene or mixture
26 product thereof is able to impart the desired level of stickiness and viscosity to the final

1 dental whitening composition in combination with the other components within the dental
2 whitening composition.

3 In addition to carboxypolymethylene, examples of other suitable tackifying and
4 thickening agents include gums such as xanthan gum, talha gum, tragacanth gum, locust bean
5 gum, guar gum, Irish moss gum, ghatti gum, furcelleran gum, carrageenan gum, arabic gum,
6 alginic acid gum, agar gum, and alginate gum, as well as proteins, such as collagen, or
7 cellulosic ethers. Another suitable tackifying agent is sold as PEMULEN®, a proprietary
8 compound from B.F. Goodrich, or a compositional or chemical equivalent thereof.
9 PEMULEN® includes a significant quantity of a polyacrylic copolymer that has a slightly
10 hydrophobic end and a strongly hydrophilic end. Additional examples of suitable tackifying
11 agents include polyethylene oxides such as POLYOX® sold by Union Carbide. These
12 tackifying agents may be present in the same ranges as discussed above in relation to
13 carboxypolymethylene.

14 Examples of suitable bleaching agents include aqueous hydrogen peroxide,
15 carbamide peroxide, benzoyl peroxide, glyceryl peroxide, percarbonates and perborates of
16 alkali and alkaline earth metals (*e.g.*, sodium perborate) and peroxyacetic acid. A significant
17 advantage of using potassium nitrate as an opacifying agent in combination with a bleaching
18 agent in a tooth whitening composition is that the potassium nitrate simultaneously decreases
19 the sensitivity of the teeth that may result from the use of the bleaching agent. The bleaching
20 agents are preferably included in a range from about 0.5% to about 50% by weight of the
21 dental whitening composition, more preferably in a range from about 1% to about 30% by
22 weight and most preferably in a range from about 3% to about 20% by weight.

23 In order to preserve the stability of the dental whitening compositions, it is often
24 preferable to include an ion scavenger such as EDTA, salts of EDTA such as edetate
25 disodium, oxine EDTA, calcium disodium EDTA, and others. Additionally, ion scavengers
26 such as citric acid, succinic acid, adipic acid, nitrates and phosphates of tin and any other

1 commonly-used chelating agents may be used. Ion scavengers are preferably included in an
2 amount in a range from about 0% to about 1% by weight of the dental whitening
3 composition, more preferably in a range from about 0.03% to about 0.5% by weight and most
4 preferably in a range from about 0.05% to about 0.2% by weight.

5 It may also be preferable to include other active dental agents to provide other types
6 of dental and/or gum treatment. For example, in conjunction with dental desensitization
7 and/or opacification, it may be desired to provide an anticariogenic treatment. Preferred
8 anticariogenic and antidemineralizing agents include fluoride salts, more particularly sodium
9 monofluorophosphate, sodium fluoride, and stannous fluoride. Depending on the level of
10 fluoride treatment desired, and depending on whether or not a composition is "over-the-
11 counter" or "by prescription", the fluoride will be included in a range from about 0% to about
12 1% by weight of the dental whitening composition, more preferably in a range from about
13 0.1% to about 0.5% by weight.

14 Antimicrobial agents, e.g., for fighting gum disease, may be included in conjunction
15 with the potassium nitrate or other opacifying agent. Examples of useful antimicrobial
16 agents include chlorohexidine, tetracycline, cetyl pyridinium chloride, benzalkonium
17 chloride, cetyl pyridinium bromide, methyl benzoate, and propyl benzoate. The
18 antimicrobial agents are preferably included in an amount in a range from about 0% to about
19 15% with the dental whitening composition, more preferably in a range from about 1% to
20 about 5% by weight.

21 As indicated hereinabove, the dental whitening compositions of the present
22 invention preferably do not include an abrasive. Abrasives only externally treat a tooth;
23 however, it is believed that whitening and opacification of a tooth is achieved by the action
24 of the bleaching agent and potassium nitrate internally within a tooth. Not only are abrasives
25 unnecessary but inclusion of abrasives in the composition may be undesirable in preferred
26 embodiments where it is desired for the whitening composition to remain on the teeth for an

1 extended period of time (*i.e.*, greater than about 3 minutes). In any event, it is common
2 experience that toothpastes become quickly diluted by saliva and will not persist in a paste-
3 like form for more than a short period of time (*i.e.*, for more than about a minute).

4 Other suitable tooth desensitizing agents that may be used in addition to potassium
5 nitrate according to the present invention include citric acid, citric acid salts, strontium
6 chloride, and the like, as well as other desensitizing agents known in the art. The amount of
7 desensitizing agent included within the dental whitening compositions of the present
8 invention may vary according to the concentration of the potassium nitrate, the desired
9 strength and intended treatment times. Accordingly, if included at all, the other desensitizing
10 agents will preferably be included in an amount in a range from about 0.1% to about 10% by
11 weight of the dental desensitizing composition, more preferably in a range from about 1 to
12 about 7% by weight.

13 One currently preferred method of dispensing preferred sticky and viscous dental
14 whitening compositions within the scope of the present invention is by means of a syringe.
15 Squeezable tubes and other similar dispensing devices may also be used to dispense the
16 compositions. Upon dispensing, preferred dental whitening compositions are sufficiently
17 viscous that they do not easily settle or spread once dispensed, but will generally remain as
18 a single extruded strand or bead of dental whitening composition. Nevertheless, bottles,
19 tubes or other dispensing means known in the art may be used, particularly where the
20 whitening composition has lower viscosity, low stickiness, and/or does not include a
21 thickening agent.

22 It is currently preferred to provide a unit dose of the dental whitening compositions
23 in a syringe or similar dispensing device. In this way, the person can load the precise amount
24 of dental whitening composition onto the dental tray for each treatment period. By using
25 such dispensing devices, the dentist is also able to monitor how many doses the person has
26 received and used.

1 depositing the dental whitening composition into dental tray 50 as shown in Figure 5 is the
2 preferred method, the dental whitening composition may also alternatively be deposited
3 directly onto the teeth and then tray 50 may be positioned on the teeth of arch 70.

4 From practice, it has been found that patients may experience less tooth discomfort
5 from tray pressures when using a tray with reservoirs built into the tray as described above.
6 It is currently believed this is due to the fact that the teeth are not held as firmly by the tray,
7 so "orthodontic" pressures experienced by teeth from tray discrepancies are minimized. The
8 use of thin, soft tray materials minimize mechanical forces applied to teeth or gums
9 compared to the harder or thicker plastics known in the art. Reservoirs, of course, can
10 provide more of the dental whitening composition against the person's teeth and can also
11 assist in seating the dental tray over the person's teeth.

12 Although the aforementioned thin, flexible dental trays are preferred when treating
13 a person's teeth, it may be preferable in some cases to allow the dental tray to overlap the
14 person's gums in the case where dental agents are included to fight gum diseases. Of course,
15 to the extent that the dental whitening compositions do not irritate the gums, the dental trays
16 can always be constructed to overlap the gums.

17 Nevertheless, it has been found that where it is desired to treat a person's teeth rather
18 than the gums, it is generally more comfortable for the patient if the dental tray has been
19 trimmed to or below the gingival margin. Even in those cases where the dental trays will
20 overlap the person's gums, the dental trays of the present invention preferably will not exert
21 significant mechanical pressure onto the person's gums.

22 Accordingly, the dental whitening compositions will preferably have a stickiness
23 such that they can reliably adhere and retain a dental tray over a person's teeth for at least
24 about one hour without significant mechanical pressure from the dental tray, more preferably
25 for at least about two hours, and most preferably for at least about four hours. Nevertheless,
26 while the foregoing time durations are given in order to provide an accurate measurement of

1 the stickiness of the dental whitening compositions of the present invention, they should not
2 be taken to be a limitation as to the actual length of time that the patient may wish to use the
3 inventive dental whitening compositions. While a given dental whitening composition may
4 be able to retain the dental tray against a person's teeth for, *e.g.*, 10 hours or more, that
5 composition could certainly be used within the scope of the present invention for any desired
6 time period, such as for 15 minutes, one hour, or any desired time duration.

7 The desensitizing dental whitening compositions of the present invention may be
8 used at any time and for any duration by a person that desires to whiten his or her teeth.
9 Although the dental whitening compositions of the present invention facilitate the use of
10 flexible, thin-walled dental trays that are more comfortable to use compared to prior dental
11 trays, the insertion of any dental tray within a person's mouth will cause some alteration of
12 behavior and diminution of the freedom to use one's mouth. Therefore, in order to maximize
13 treatment time and reduce the inconvenience of having a dental tray lodged within a person's
14 mouth, it is recommended to use the dental trays at night during a person's sleep.

15 It has been found that optimal results are achieved from cyclic exposure periods
16 involving repeated exposures over several days or weeks. For example, the treatment regime
17 may alternatively entail exposure for a period of time such as an hour without further
18 exposure until the subsequent day. For day use, it is recommended that the whitening
19 compositions be applied for about 1 to 3 hours. The length of the treatment period during
20 night use may vary with the sleep pattern of the particular person and may accordingly be
21 between about 5 to 9 hours.

22 In order to more clearly illustrate the parameters of the inventive dental whitening
23 compositions within the scope of the present invention, the following examples are
24 presented. The following examples are intended to be exemplary and should not be viewed
25 as limiting to the scope of the invention.
26

EXAMPLE 1

A whitening composition within the scope of the invention was prepared by combining the following ingredients in the following proportions, measured as percentage by weight of the whitening composition:

CARBOPOL 974P NF	6.8%
Glycerin	48.45%
Polyethylene glycol 300	5.5%
Water	20.0%
Sodium hydroxide (50%)	5.4%
KNO ₃	3.0%
Carbamide peroxide	10.5%
Disodium EDTA	0.1%
NaF	0.25%

The CARBOPOL 974P NF was obtained from B.F. Goodrich Company in Cleveland, Ohio. The CARBOPOL 974P NF was first combined with the glycerin and polyethylene glycol 300 then mixed with the water. Mixing glycerin and polyethylene glycol 300 within the CARBOPOL 974P NF enabled it to be more easily mixed with the water. The KNO₃, carbamide peroxide and disodium EDTA were added to the mixture, after which the sodium hydroxide was blended into the homogeneous composition in order to raise the pH to an acceptable level. The sodium fluoride was then added. The resulting dental whitening composition was found to have opacifying, bleaching, desensitizing and anticariogenic properties, and was sufficiently sticky that it could reliably hold and maintain a dental tray against a person's teeth without significant mechanical pressure being exerted by the tray onto a person's teeth and gums.

EXAMPLE 2

A preferred dental whitening composition within the scope of the present invention was made according to the procedure of Example 1, except that the ingredients were combined in the following concentrations by weight percent:

CARBOPOL 974P NF	6.8%
Glycerin	35%
Polyethylene glycol 300	5.5%
Water	20%
Sodium hydroxide (50%)	5.8%
KNO ₃	0.5%
Carbamide peroxide	10.5%
Disodium EDTA	0.3%
Peppermint Flavor	0.6%
Xylitol	15%

The resulting dental whitening/desensitizing composition was tested and found to be surprisingly superior to test compositions similar to those of Example 1 that included 3% potassium nitrate. Compared to tooth whitening/desensitizing compositions that included 3% potassium nitrate, the 0.5% formulation of Example 2 exhibited greatly reduced tooth sensitivity. These included sensitivity to hot and cold, as well as general sensitivity of gums, tongue and throat. The 0.5% formulation of Example 2 also showed a dramatic increase in tooth whitening ability compared to a test composition that included no potassium nitrate, thus establishing the surprising result that potassium nitrate in minor concentrations greatly increases the whitening effect of the dental bleaching composition.

COMPARATIVE STUDY

The composition of Example 2 was the subject of a comparative study comparing the desensitizing and bleaching ability of the composition of Example 2 to four other dental bleaching compositions. In the study, the five dental compositions were labeled as compositions A-E, respectively, with composition E being the composition of Example 2. The dental bleaching compositions were applied using custom dental trays made to fit each patient. Compositions A-D were similar to the composition of Example 2, except that they included differing amounts of carbamide peroxide and potassium nitrate and, in one case, a different sweetener:

<u>Composition</u>	<u>Carbamide Peroxide</u>	<u>KNO₃</u>	<u>Sweetener</u>
A	10%	0%	Xylitol
B	10%	3%	Xylitol
C	10%	3%	Aspartame
D	15%	3%	Xylitol

The results of the comparative study are set forth in Table 1.

Table 1

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

As clearly demonstrated by the data set forth in Table 1, the comparative study showed a dramatic decrease for composition E in the number of days that patients experienced hot or cold sensitivity compared compositions A-D. Surprisingly, even though potassium nitrate was heretofore believed to be a desensitizing agent at any concentration, when mixed with a dental bleaching agent at a concentration of 3% (compositions B-D), it actually **increased** patient tooth sensitivity compared to composition A, which included no potassium nitrate. This demonstrated that potassium nitrate, when blended with a dental bleaching agent and used, does not behave as a desensitizing agent but instead increases sensitivity at certain concentrations (e.g. 3%). Even more surprisingly, composition E resulted in an average Vita tab shade change of 8.6, which was even more than any of compositions A-D, including composition D, which included approximately 50% more

1 bleaching agent than composition E, thus demonstrating the surprising result that including
2 lower concentrations of potassium nitrate increases whitening of teeth compared to
3 compositions that either include no potassium nitrate or those which include 3% potassium
4 nitrate.

6 EXAMPLES 3-10

7 Dental whitening compositions within the scope of the present invention are made
8 according to Example 1, except that the concentration of KNO_3 is included in the following
9 amounts: 0.01%, 0.05%, 0.1%, 0.3%, 0.75%, 1%, 1.5% and 2%. The resulting dental
10 bleaching compositions would be expected to have exhibit superior bleaching with less
11 sensitivity compared to dental bleaching compositions that include no potassium nitrate.

13 EXAMPLE 11

14 Dental whitening compositions within the scope of the present invention are made
15 according to Example 2, except that at least a portion of the glycerin is replaced by propylene
16 glycol.

18 EXAMPLE 12

19 Dental whitening compositions within the scope of the present invention are made
20 according to Example 2, except that the CARBOPOL 974 NF is included in the following
21 amounts: 0%, 0.5%, 2%, 3%, 5%, 10% and 20%. The concentration of NaOH (50%) is
22 adjusted accordingly to maintain approximately the same pH as in Example 2.

24 EXAMPLE 13

25 Dental whitening compositions within the scope of the present invention are made
26 according to Example 12, except that all or part of the CARBOPOL 974 NF is replaced by

EXAMPLE 15

To any of the foregoing dental whitening compositions is added one or more of the following antimicrobial agents for treatment of a patient's gums: chlorohexidine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methyl benzoate, and propyl benzoate. These compositions are preferably used in conjunction with a thin walled, flexible dental tray that overlaps the person's gums in order for the dental whitening compositions to contact the gums being treated.

EXAMPLE 16

To any of the foregoing dental whitening compositions which include a bleaching agent and do not include a bleaching agent stabilizer, one of the following chelating agents may be added: EDTA, monosodium EDTA, citric acid, succinic acid, and adipic acid.

From the foregoing, it will be appreciated that the present invention provides compositions and methods for whitening teeth, including compositions and methods for opacifying excessively translucent teeth.

The present invention also provides compositions for whitening and opacifying teeth which reduce tooth sensitivity compared to conventional dental bleaching compositions.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Letters Patent is: